Remarks

The Office Action mailed May 10, 2007 has been received and reviewed. Claims 1, 18, 32, and 50 have been amended. Claims 14, 15, 29, 46, 47, 64, and 65 were previously canceled, without prejudice. Pending claims are claims 1-13, 16-28, 30-45, 48-63, 66, and 67. Reconsideration and withdrawal of the rejections are respectfully requested.

Amendments to the Claims

Claims 1, 32, and 50 have been amended to indicate that the claimed devices "have materials distributed in one or more separate agent delivery devices contained within the lumen of said shunt, wherein said agent delivery device(s) is selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof."

Claim 18 was similarly amended for the claimed cannula, wherein the cannula can "have materials distributed in one or more separate agent delivery devices contained within the lumen of said cannula, wherein said agent delivery device(s) is selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof."

The amendments are fully supported by Applicants' disclosure. Support for claiming agent delivery devices contained within the lumen of either a shunt (Claims 1, 32, or 50) or a cannula (Claim 18) can be found on page 11, line 22 through page 12, line 14 and in Figures 6 and 7. Spherical agent delivery devices are described, for example, from page 10, line 29 through page 11, line 12 and Figure 3. Eluting plug agent delivery devices are described, for example, from page 11, line 22 through page 12, line 26 and in Figures 7 and 8. Seed agent delivery devices are described, for example, from page 12, line 30 through page 13, line 5 and in Figure 11. Elongated member agent delivery devices are described, for example, at page 11, lines 9-12 and in Figure 4.

No new matter is introduced by the amendments.

The 35 U.S.C. § 103 Rejections

Tweden in view of Baudino, in further view of Wu

The Examiner rejected claims 1, 3, 6, 7, 11-13, 16-18, 20, 23, 24, 28, 30-32, 34, 37, 38, 42-45, 48-50, 52, 55, 56, 60-63, 66, and 67 under 35 U.S.C. §103(a) as being unpatentable over Tweden (U.S. Patent No. 7,008,397) in view of Baudino (U.S. Patent No. 6,110,155), further in view of Wu (US6,656,506). Of the rejected claims, claims 1, 18, 32, and 50 are independent.

Applicants submit that the claims, as amended herein, are patentable over the combination of Tweden in view of Baudino in further view of Wu because the documents, when combined, fail to teach or suggest all of the features now recited in the claims.

Claims 1, 18, 32, and 50 have been amended to indicates the materials delivering the drugs are distributed in one or more separate agent delivery devices contained within the lumen of the claimed shunt, or cannula, wherein said agent delivery devices is selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof. No where in Tweden, Baudino, or Wu, singularly or collectively, is there a teaching or suggestion that separate agent delivery device(s) are used or that they are inserted within the lumen of the claimed shunt or cannula.

Applicants wish to reiterate that the device of Tweden et al. is directed to a cardiac implant that redirects the flow of blood from the myocardium to the vasculature. See

figure 1 and related text.

> Column 4, lines 15-17 – "The first portion 26 is dimensioned to extend from the vasculature 36 through the myocardium 32 and into a heart chamber 38.

As such, Tweden's cardiac implant device needs to be constructed as a solid conduit for carrying blood from the heart chamber to the vasculature – if not the blood would leak into the surrounding tissue (see Tweden's Figures 1-6).

Another distinction between the claimed invention and that of Tweden et al is that Tweden et al specifically indicates having an external wrapping of material around the main conduit. The purpose of the external wrapping is to facilitate tissue in growth to stabilize the conduit:

> Column 4, lines 31-35 – "The material 44 surrounds the exterior of the conduit 12 and may be a polyester woven cuff 45 or sintered metal to define pores into which tissue growth from the myocardium 32 may occur."
>
> Column 4, lines 58-60 – "The implant 60 includes a sleeve 66 of tissue growth inducing material secured to an exterior surface of the conduit 62."
>
> Column 5, lines 51-58 – "As discussed more fully in U.S. Pat. No. 5,984,956, the rigid conduit 62 may be provided with tissue-growth producing material 82 adjacent the upper end of the conduit 62 to immobilized the conduit 62 with the myocardium 32. The material 82 surrounds the exterior of the conduit 62 and may be a polyester woven cuff 83 or sintered metal to define pores into which tissue growth from the myocardium may occur."

A third distinction regarding Tweden is that Tweden is trying to promote in-growth and intimate tissue-device adhesion. With shunts and cannulas the Applicants are trying to do the exact opposite.

The present invention is directed to having agent eluting devices present in the internal conduit (not externally wrapped around the conduit). Tweden specifically requires the external wrap for delivering of drugs to facilitate external tissue in-growth to the external portion of the

device in order to stabilize it into the tissue. Other than the central shaft, no apertures penetrate the conduit of Tweden et al.

Baudino was cited for disclosing a catheter comprising a conduit 14 with a plurality of apertures 32 at the distal end to improve fluid flow between the lumen 20 and the outside of the catheter (see Fig. 2, column 3, lines 20-30) and that the catheter 14 may comprise a medicament that is dispersed throughout the polymeric catheter, allowing the medicament to diffuse into the patient from the interior and exterior of the catheter, preventing inflammation and blockage both inside and outside the catheter (see column 3, line 45 to column 4, line 7). As previously stated, the purpose of Applicant invention is to prevent ingrowth by providing inhibitory agents in the internal lumen of the device. Baudino describes a infusion catheter. As such Baudino is not concerned about tissue in-growth as there is a net flow of material from inside the catheter to the outside the catheter. In our instant invention, the shunt or cannula system is not used to infuse drugs, rather it is used to transport cerebral spinal fluid from inside the brain to another location in the body. The net flow is the opposite direction from outside to inside. This flow direction can draw cells and attached inside the lumen of the catheter where it can continue to grow, if not attenuated by drugs provided by Applicants invention, until lumen blockage occurs.

Assuming for a moment the teachings of Baudino, or Tweden in view of Baudino, there is no teaching or suggestion with either reference of having agent delivery devices contained within lumen a shunt or cannula. Further, neither reference teaches that the separate agent delivery devices are selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof. Baudino only teaches to impregnate the wall, not to place a separate agent delivery device internally. Tweden has no teaching regarding the release of an active agent.

Wu was cited for teaching the agent delivery devices comprising spheres, plugs, seeds, rods, or combinations thereof. Applicants respectfully disagree that Wu teaches any of the above. Wu's teaching is related to drug-loaded microparticles that can be incorporated onto the surface of a medical device. The drug coated microspheres are applied onto a medical device by dipping the device into a polymer matrix so that a coating of the polymer matrix has a relatively smooth surface texture over the entire surface. Alternatively, Wu teaches the medical device can be spray coated with a polymer matrix. Coating a medical device by either method with a polymer matrix does not lead or render obvious Applicants Invention of having one or more separate agent delivery devices contained within the lumen of the shunt or cannula. Applicants contend that Wu's reference to a microsphere or nanosphere is related to drug particles contained within a coating. Spheres of the present invention are agent delivery devices contained within the lumen of device. Applicants content there spheres can not be equated with having microspheres or nanospheres coated onto the inner or outer surface. Applicants draw the attention of the Examiner to Figures 2-13 of their specification where the separate agent delivery devices contained within the lumen of the device can not be confused with being a coated microsphere or nanosphere on the wall of the shunt or cannula. This distinction is further indicated by Applicants specified agent delivery devices being chosen between spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof.

Each of claims 3, 6, 7, 11-13, 16, and 17 depends, directly or indirectly, from Claim 1; each of Claims 20, 23, 24, 28, 30, and 31 depends, directly or indirectly, from Claim 18; each of Claims 34, 37, 38, 42-45, 48, and 49 depends, directly or indirectly, from Claim 32; and each of Claims 52, 55, 56, 60-63, 66, and 67 depends, directly or indirectly, from Claim 50. Each is, therefore, patentable for at least all of the reasons that its independent claim is patentable.

Therefore, Applicants submit that claims 1, 3, 6, 7, 11-13, 16-18, 20, 23, 24, 28,

30-32, 34, 37, 38, 42-45, 48-50, 52, 55, 56, 60-63, 66, and 67 are patentable under 35 U.S.C. §103(a) over Tweden in view of Baudino, in further view of Wu.

Kraus in view of Baudino in Further View of Wu

The Examiner rejected claims 2, 4, 5, 19, 21, 22, 33, 35, 36, 51, 53, and 54 under 35 U.S.C. §103(a) as being unpatentable over Kraus (U.S. Patent No. 5,925,182) in view of Baudino (U.S. Patent No. 6,110,155), in further view of Wu (US Patent No. 6,656,506).

Each of the rejected claims depends, directly or indirectly, from one of the amended independent Claims 1, 18, 32, or 50. Applicants submit the claims are patentable over the combination of Kraus in view of Baudino in further view of Wu because the documents, when combined, fail to teach or suggest all of the features recited in the claims.

The combination of Kraus, Baudino, in Wu fails to teach or suggest that the delivered the drugs are "distributed in one or more separate agent delivery devices contained within the lumen of the device wherein the inserted delivery devices are selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof." No where in Kraus, Baudino, or Wu is their a teaching or suggestion that separate agent delivery devices are used or that they are inserted within the cited device.

Applicants have previous discussed the limitations of Baudino, and Wu. Kraus adds little to contribute to the limitations of Baudino and Wu. Kraus teaches a shunt comprising a conduit with inflow and outflow ends (see Fig. 6) that comprises a valve to control fluid flow and that the valve may be made of silicone or polyurethane to enhance biocompatibility. Although Applicants invention may include a valve, it is not part of the patentability of Independent Claims 1, 18, 32, and 50. As previously discussed, Baudino and Wu fail to teach

having a separate elution device contained with in the shunt or cannula.

. Thus, the combination of Kraus, Baudino, and Wu fails to set forth each and every element of the claims and, therefore, fails to set forth a *prima facie* case of obviousness. Applicants submit that claims 2, 4, 5, 19, 21, 22, 33, 35, 36, 51, 53, and 54 are patentable under 35 U.S.C. §103(a) over the combination of Kraus in view of Baudino.

Tweden in view of Baudino, in view of Wu, further in view of Hunter et al.

The Examiner rejected claims 8-10, 25-27, 39-41, and 57-59 under 35 U.S.C. §103(a) as being unpatentable over Tweden (U.S. Patent No. 7,008,397) in view of Baudino (U.S. Patent No. 6,110,155), in view of Wu (U.S. Patent No. 2005/0208095) further in view of Hunter et al. (U.S. 2005/0208095 A1).

Each of the rejected claims depends, directly or indirectly, from one of the amended independent claims. The deficiencies of the combination of Tweden in view of Baudino, in view of Wu are described in detail above. These references taken together in further view of Hunter et al. fails to cure the deficiencies of Tweden, Baudino, and Wu.

Hunter, was cited for disclosing a method of treating patients with various conditions by providing an implantable medical device comprising providing a therapeutic agent to a patient and allowing the therapeutic agent to elute into the patient (see, generally, para. 0014). In an embodiment, the therapeutic material may comprise mycophenolic acid in order to inhibit fibrosis (see para. 0223).

The fact that Hunter discloses use of mycophenolic acid as a therapeutic agent fails to over come the deficiencies of Tweden in view of Baudino previously discussed. No

where do any of these references teach or suggest, singularly or in combination, that the delivered the drugs are "distributed in one or more separate agent delivery devices contained within the lumen of the device wherein the inserted delivery devices are selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof." Further, Applicants use of myophenolic acid is used to preventing in-growth of neural tissue such as the choroid plexus, the ependymal lining of the ventricles, glial cells, vasculature and other already present tissue. Applicants invention is not directly directed to preventing fibrosis, as this is not a common cause of occlusion for shunts and cannulas.

Thus, the combination of Tweden in view of Baudino, further in view of Hunter et al., fails to set forth each and every element of the claims and, therefore, fails to set forth a *prima facie* case of obviousness.

Applicants submit that claims 8-10, 25-27, 39-41, and 57-59 are patentable under 35 U.S.C. §103(a) over Tweden in view of Baudino, further in view of Hunter et al. Therefore, Applicants submit that claims 1-13, 16-28, 30-45, 48-63, 66, and 67 are patentable under 35 U.S.C. § 103.

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for,

Edouard KOULLICK et al.

November 9, 2007
Date

By: Kenneth J. Collier
Kenneth J. Collier
Registration No. 34,982
Telephone Number: (763) 505-2521
Facsimile Number: (763) 505-2530
CUSTOMER NUMBER: 27581